

**Notice of Allowability**

Application No.

09/978,272

Applicant(s)

LASSEN ET AL.

Examiner

Mary E. Mosher, Ph.D.

Art Unit

1648

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 2/9/2004.
2. ☒ The allowed claim(s) is/are 1-3, 8-28, 30-43 and 45-76.
3. ☒ The drawings filed on 17 January 2001 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Iver Cooper on 17 May 2004.

The application has been amended as follows:

Claim 1 has been amended to more clearly define the invention, and claims 45-47 have been amended to be consistent with amended claim 1. See the attached sheet for the amendments to claims 1 and 45-47.

An additional examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. The specification has been amended to insert a brief description of the figures. See the attached sheet for the amendment.

The abstract by Sheeran et al, cited in the previous Office action, was accidentally omitted from the PTO-892, and no copy was scanned into the image file. To correct this error, the reference is now cited on the attached 892 and another copy is provided in hopes that it will be scanned into the image file record.

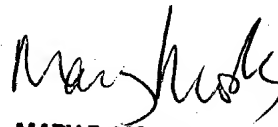
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

5/17/04

  
**MARY E. MOSHER**  
**PRIMARY EXAMINER**  
**GROUP 1800** 1602

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Amendments to claims 1, 45, 46, and 47

Claim 1. (currently amended). A kit for directly detecting a respiratory syncytial (RS) virus infected cell or an RS virus biological particle present in a sample in an amount of less than about 2000 cells or particles per microlitre ( $10^{-6}$  litre), said kit comprising

i) a solid support comprising an application zone for applying the sample and a separate detection zone, and

ii) a conjugate comprising a polymeric carrier molecule bound to

a) at least one targeting species capable of directly binding an RS virus infected cell or RS virus biological particle, and

b) at least one labelling species,

wherein the application zone and the detection zone can form a liquid contact, the application zone comprises at least one of said conjugate, said conjugate being movable, and the detection zone comprises at least one targeting species which is bound to the solid support and is capable directly of binding an RS virus infected cell or RS virus biological particle.

~~—— i) a solid support, and~~

~~—— ii) a plurality of a first targeting species bound to the solid support, said targeting species being capable of directly binding a predetermined RS virus infected cell or biological particle when it is present in a sample that is brought into contact with the solid support, and~~

- ~~iii) a conjugate comprising a polymeric carrier molecule bound to
  - a) at least one targeting species capable of directly binding a predetermined RS virus infected cell or biological particle when it present in a sample that is brought into contact with the solid support, and
  - b) at least one labelling species,~~
- ~~iv) an application zone for applying the sample comprising a RS virus infected cell or biological particle, said zone comprising at least one of said conjugate, said conjugate being movable, and said application zone being in liquid contact with~~
- ~~v) a detection zone, separate from said application zone, for detecting the presence, amount or concentration of said at least one conjugate, said zone further comprising at least one targeting species bound to the solid support.~~

45 (currently amended). The kit according to claim 1 further comprising vi) a positive control zone comprising means for generating a positive control confirming the transfer of at least part of said sample from said application zone to said detection zone.

46 (currently amended). The method of claim 24, said kit further comprising vi) a positive control zone comprising means for generating a positive control confirming the transfer of at least part of said sample from said application zone to said detection zone.

47 (currently amended). The method of claim 43, said kit further comprising vi) a positive control zone comprising means for generating a positive control confirming the transfer of at least part of said sample from said application zone to said detection zone.

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Amendment to the specification

In the specification, the following has been inserted after page 9, line 33:

**Brief Description of the Figures**

FIG. 1 illustrates a schematic dipstick, for use in an assay for testing detecting of RS related cell in a sample. The dipstick comprises an application zone for the sample comprising the reporter species. The term conjugate refers to reporter species.

Fig. 2 illustrates a dipstick developed so that a red test line appears across the membrane instead of a red spot, both for observing the test result and the control.